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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,738	09/17/2001	Hans Konrad Schackert	012627-025	8967
21839	7590	10/22/2003	EXAMINER	
BURNS DOANE SWECKER & MATHIS L L P			WHISENANT, ETHAN C	
POST OFFICE BOX 1404			ART UNIT	
ALEXANDRIA, VA 22313-1404			PAPER NUMBER	
			1634	

DATE MAILED: 10/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/936,738	SCHACKERT ET AL.	
	Examiner	Art Unit	
	Ethan Whisenant, Ph.D.	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) 19-26 and 32-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17, 27, 30 and 31 is/are rejected.
- 7) ☐ Claim(s) 18, 28 and 29 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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NON-FINAL ACTION

1. The applicant's election of Group I (**Claims 1-18 and 27-31**) with traverse in the paper filed 16 DEC 02 is acknowledged. Claims 19-26, and 32-52 are withdrawn from further consideration as being directed toward a non-elected invention.

The traversal of the restriction requirement appears to be based on the applicant's contention that the special technical feature which unites the claimed invention (i.e. causes the claims to have unity of invention) is that the method utilizes the highly conserved PTEN gene. However the examiner respectfully points out that there are no limitations in Claim 1 which limit the method to the highly conserved PTEN gene. Rather, as noted previously, the claims **as drawn** are related to each other because they relate to a method of identifying organisms by comparative genetic analysis. However, since this method (i.e. Claim 1), **as claimed**, was known - see, for example, Jensen et al [US 5,753,467 (MAY 1998)] and/or Rogan [US 5,849,492 (DEC 1998)] - the claims are no longer linked by a special technical feature, because, by definition, the special technical feature must distinguish over the prior art. Without the special technical feature the claims lack unity. The examiner readily admits that neither Jensen et al. or Rogan teach using the highly conserved PTEN gene in their methods of, however, this limitation is not recited in Claims 1-9, therefore, the applicant cannot rely on this limitation as the special technical feature. In view of this finding and after carefully review of the Lack of Unity requirement, the applicant's traversal thereof, the restriction requirement is deemed proper and it is herein made **FINAL**.

IDS

2. The information disclosure statement filed 17 SEP 01 **fails to fully comply** with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. Please note that the German patent 196 29 166 listed in the IDS has been placed in the application file, but the information therein has not been considered.

SPECIFICATION

- 3.** The specification is objected to because of the following informality. In order to comply fully with the sequence rules: all nucleotide and/or amino acid sequences recited in the specification should be accompanied by their corresponding SEQ ID NOs. Appropriate correction is required.

CLAIM OBJECTIONS

- 4.** **Claim(s) 28-29** is/are objected to because of the following informality. In order to comply fully with the sequence rules: all nucleotide and/or amino acid sequences recited in the claims should be accompanied by their corresponding SEQ ID NOs. Appropriate correction is required.

DRAWINGS

- 5.** The drawings are objected because, for example, the text present inside the boxes in Figure 1 is illegible. Also, In order to comply fully with the sequence rules: all nucleotide and/or amino acid sequences recited in the figures should be accompanied by their corresponding SEQ ID NOs. Formal drawings are now required in response to this Office Action. See Section #10 on the attached PTOL-326.

SEQUENCE RULES

- 6.** As regards the filing of a paper copy of the sequence listing and the corresponding CRF, this application now complies with the sequence rules. The sequences have been entered by the Scientific and Technical Information Center.

35 USC § 112- 2ND PARAGRAPH

- 7.** The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

CLAIM REJECTIONS under 35 USC § 112- 2ND PARAGRAPH

- 8.** **Claim(s) 2-4** is/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is indefinite because of the use of the word "preferably ...". The use of exemplary claim language makes these claims indefinite. See the MPEP at 2173.05(d).

It is well established that the description of examples or preferences is properly set forth in the specification rather than the claims. If stated in the claims, examples and preferences lead to confusion over the intended scope of a claim. Ex parte Hall, 83 USPQ 38 (Bd. App. 1949).

In addition, **Claim 2** is indefinite because of the phrase "in as many studied species DNAs as possible" on line 5. It is unclear what is intended.

Claim 3 is indefinite because this claim recites that the coding and/or non-coding areas located between the primers are highly variant. However, in Claim 1 the coding and/or non-coding areas located between the primers (i.e. regions amplified) are highly conserved. Therefore, it is unclear how Claim 3 further limits Claim 1. Please clarify.

Claim 4 is indefinite because of the phrase "or also" on lines 2-3. It is unclear what is intended. Please clarify.

35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that may form the basis for rejections set forth in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) The invention was described in --

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a)

CLAIM REJECTIONS UNDER 35 USC § 102

10. Claim(s) 1-2, 4, 9-17, 27 and 30-31 is/are rejected under 35 U.S.C. 102(b) as being anticipated by Jensen et al [US 5,753,467 (MAY 1998)].

Jensen et al. teach a method of identifying organisms by comparative genetic analysis comprising all of the limitations recited in Claims 1-2, 4, 9-17, 27 and 30-31. See, at least, Column 4 - Column 9, line 20. As regards the rejection of Claims 10-14, 16-17 and 31 the examiner has interpreted the term "homologues" broadly to include the rRNA of Jensen et al.

11. Claim(s) 1-2, 4-7, 9-17, 27 and 30-31 is/are rejected under 35 U.S.C. 102(b) as being anticipated by Davidson et al. [WO9205277 (1992)].

Davidson et al. teach a method of identifying organisms by comparative genetic analysis comprising all of the limitations recited in Claims 1-2, 4-7, 9, 15, 27 and 30-31. See, at least, p.13, line 46 - p.18, line 8. As regards the rejection of Claims 10-14, 16-17 and 31 the examiner has interpreted the term "homologues" broadly to include the mitochondrial sequences disclosed by Davidson et al.

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12. Claim(s) 1-2, 4-17, 27 and 30-31 is/are rejected under 35 U.S.C. 102(e) as being anticipated by Rohde [US 6,294,329 (2001)].

Rohde teaches a method of identifying organisms by comparative genetic analysis comprising all of the limitations recited in Claims 1-2, 4-17, 27 and 30-31. See, at least, the claims. As regards the rejection of Claims 10-14 and 16-17, and 31 the examiner has interpreted the term "homologues" broadly to include the 1.4 kbp copia-like element disclosed by Rohde.

CLAIM OBJECTIONS

13. As regards the prior art, Claim(s) 18, and 28-29 are objected to because they are dependent upon a rejected independent base claim.

CONCLUSION

14. Claim(s) 1-18 and 27-31 is/are rejected and/or objected to for the reason(s) set forth above.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (703) 308-6567. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

The fax number for this Examiner is (703) 746-8465. Before faxing any papers please inform the examiner to avoid lost papers. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989). Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist whose telephone number is (703) 308-0196.


ETHAN WHISENANT
PRIMARY EXAMINER